DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

December 11, 2015

Prowess, Inc.
% Ms. Rachel Scarano
Regulatory Affairs Manager
1844 Clayton Road
CONCORD CA 94520

Re: K143514
Trade/Device Name: Panther StereoSeed
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: MUJ
Dated: November 20, 2015
Received: November 23, 2015

Dear Ms. Scarano:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143514

Device Name
Panther StereoSeed

Indications for Use *(Describe)*
The Panther StereoSeed module is intended to create a plan that is optimized for seed locations and needle directions, allowing needles to be inserted in any angle in order to avoid critical structures.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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PROWESS

May 4, 2015

510(k) SUMMARY

As required by 21 CFR Part 807.92

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1. Submitter:

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Contact Person:

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Device Manufacturer:

Prowess Inc.
1844 Clayton Road
Concord, CA 94520

2. Device Trade Name: Panther StereoSeed

Classification Name: Medical charged-particle radiation therapy system (21 CFR § 892.5050), Class II

Establishment Reg. No.: 2939248

Common Name: Radiation Therapy Treatment Planning System, Brachytherapy

Product Code: MUJ

Predicate Devices: MIM Software Inc's MIM 5.2 (Brachy), K103576, Product code LLZ
Varian Medical System's VariSeed 7.0, K012017, product code MUJ

3. Device Description

Panther StereoSeed is an optional software module that has been added to the existing Prowess Panther Brachy system to produce a seed implant plan that is optimized for seed locations and needle directions. The key distinction between Panther StereoSeed and traditional brachytherapy systems is that StereoSeed allows plans to be created such that bones and critical structures can be avoided.

4. Intended Use

Panther StereoSeed is intended to create a plan that is optimized for seed locations and needle directions, allowing needles to be inserted in any angle in order to avoid bones and critical structures.

5. Summary of Comparisons to Predicate Devices

Panther StereoSeed is substantially equivalent to predicate devices, MIM 5.2 (Brachy) by MIM Software Inc. and VariSeed 7.0 by Varian Medical Systems, Inc. for the purposes of premarket clearance, as demonstrated and documented in this premarket notification submission. In addition, the rationalization for substantial equivalence is further evidenced through discussion of similar technological characteristics between StereoSeed and the predicates, as well as test results, which prove that Panther StereoSeed is as safe and effective as the predicate devices.

6. Summary of Technological Considerations

Panther StereoSeed has many of the same technological characteristics as the predicate devices. There is a limited amount of distinguishing factors when comparing StereoSeed to the predicates, and those features that are different do not affect safety or effectiveness. This is described in detail in Section VIII: Substantial Equivalence Comparison.

7. Summary of Non-clinical Tests

A hazard analysis was conducted, and associated documentation is included in Section XI. Methods for preventing and/or mitigating defined hazards are detailed in Section X: Software Verification & Validation. Verification and validation of the software was performed in-house according to established test plans and protocol, which have been included in Section IX as well. Functional testing was conducted both in-house and at the Department of Minimal Invasive Cancer Center of Inner Magnolia Cancer Hospital (IMCH) in Hohhot City, China. In addition, relevant regression testing was conducted by Prowess Quality Assurance to ensure that changes to the software did not result in any unanticipated, negative impact on other areas of the software. Verification and validation testing has demonstrated that Panther StereoSeed has met its predetermined specifications, demonstrated substantially equivalent performance to the predicate device, functions as intended, and is safe and effective for its specified use.

8. Summary of User Site Testing

Although clinical testing is not required to demonstrate substantial equivalence in safety and effectiveness, we elected to conduct beta testing at the Department of Minimal Invasive Cancer Center of Inner Magnolia Cancer Hospital (IMCH) in Hohhot City, China using real patient cases, in order to obtain feedback and to verify the results of in-house testing in a user environment. We feel that no matter how carefully a product is tested at the manufacturer's facility, such testing cannot replace actual use of the device in a clinical setting. As such, we consider both in-house testing and beta testing at a user site during device development to verify safety and effectiveness, as well as to ensure that benefits to the patient from treatment with the device outweigh any inherent risks.

9. Labeling

The CD media labeling, Instructions for Use, Panther Brachy User Manual, and marketing material are provided in Section IX of this submission. The User Manual, in digital format, is also included in the software media and can be viewed as part of the on-line help.

Product labels comply with 21 CFR 1040.10 and 1040.11 as applicable. In addition, labeling complies with applicable requirements of 21 CFR 801, including the requirement that the device be provided with adequate directions for use.

10. Summary of Safety and Effectiveness Information

a. Prowess, Inc. is a registered medical device establishment, whose quality system meets the requirements of ISO 13485, Annex II of Medical Device Directive 93/42/EEC, and FDA's QSR, 21 CFR 820.

b. Panther StereoSeed was designed and implemented according to established Prowess Inc. established design and development, as well as quality management, procedures of Prowess Inc. In addition, design and development of the medical device software complies with internationally recognized standards including ISO 14971:2007 *Medical devices – Application of risk management to medical devices,* IEC 62304 *Medical device software – Software life cycle processes,* and IEC 62083 *Medical electrical equipment – Requirements for the safety of radiotherapy treatment planning systems.*

c. The management of the company is committed to the highest standards of quality management. The Quality Management System is subject to regular, planned and documented audits by external consultants and by the FDA.

d. A comprehensive risk analysis has been conducted. Detailed methods of mitigating these potential risks have been identified by the development team, and verified by clinical physicists contracted by Prowess and determined to be adequate.

e. The software has been verified and validated based on established testing plans. The functionalities have been tested by in-house test engineers. In addition to in-house testing, the system was also tested by our beta-site using clinical cases. Documentation of these tests is included in Section X of the submission.

f. Directions and precautions for safe and effective use are included in the Instructions for Use and User Manual. Training by a Prowess specialist is also provided as part of product distribution/installation.

11. Level of Concern

As medical device software, the submission for Panther StereoSeed follows FDA's G*uidance for the Content of Premarket Submissions for Software Contained in Medical Devices.* Since prior to mitigation of hazards, a failure of the software device could results in death or serious injury to a patient, it has been determined that the software correlates to a Major Level of Concern, and as such, the associated documentation is included in this submission.

12. Conclusions

Panther StereoSeed is substantially equivalent to the predicate devices for the purposes of FDA clearance for commercial distribution. It has the same intended use and similar technical characteristics. The software has been found to perform as intended and the benefits to patient and user outweigh any inherent risks, which has been demonstrated via in-house testing as well as in field tests. Its use does not raise any new safety or effectiveness concerns when compared to the predicates.